



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

May 13, 2020

OFFICE OF  
AIR AND RADIATION

The Honorable Bradley Schneider  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Schneider:

I am writing in response to your letter from March 27, 2020, about the U.S. Environmental Agency's (EPA) review of two regulations to address emissions of the chemical ethylene oxide: National Emissions Standards for Hazardous Air Pollutants (NESHAP) for miscellaneous organic chemical manufacturing, and the NESHAP for commercial sterilizers. I am pleased you had the opportunity to discuss the Agency's progress on these issues with Administrator Wheeler during the March 31, 2020, Congressional Ethylene Oxide Task Force call.

*Communicating about EPA rulemaking*

As EPA pursues its mission of protecting public health and the environment, addressing ethylene oxide is a high priority for the Agency. In your letter, you asked that EPA "be thinking about how to effectively communicate with the public every step of the way" as we go through the rulemaking process for the two regulations currently under review. As we discussed during our March 31 meeting, EPA has taken a number of steps to ensure an open and transparent rulemaking process. First, I signed proposed amendments to the NESHAP for miscellaneous organic chemical manufacturing (often referred to as "the MON") on November 1, 2019, and EPA made a copy of the proposed rule available on its website that same day. Second, the proposal was published in the Federal Register on December 17, 2019<sup>1</sup>. Third, EPA held two public hearings on the proposed rule: one on January 14, 2020, in Houston, Texas; and the other on January 16, 2020, in Washington, D.C. Fourth, the Agency held a public webinar to walk through the proposed rule on January 21, 2020. Finally, EPA provided a lengthy public comment period, which was extended to March 19, 2020; the public had access to the proposed rule for four and a half months prior to the comment deadline. EPA staff have been reviewing the more than 5,000 comments received on the proposed rule as they develop a final rule. EPA is under a court-ordered deadline to take final action on the MON by May 29, 2020.

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In addition, the Administrator has hired a senior advisor for risk communication at EPA headquarters. This advisor is consulting on risk communication involving ethylene oxide across the Agency; her work is supplementing the work already underway in this area by EPA's Office of Air Quality, Planning and Standards, and she is working closely with staff from that office.

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#### *The IRIS value for ethylene oxide*

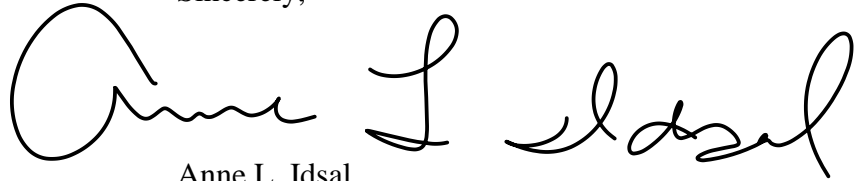
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*Addressing the diversity of industrial facility in the sterilizers rule*

Your letter encourages EPA to account for the diversity of the sterilization industry in its upcoming proposed rulemaking and asks the Agency to help small businesses comply. As we discussed in our recent meeting, about one-third of the facilities potentially affected by the sterilizers rule are small businesses. Because of this, we have convened an SBAR panel, which is expected to provide recommendations by late summer. The proposed regulation will include an appropriate time for facilities to comply, and EPA will provide compliance assistance. I also wish to note that section 112 of the CAA allows the Administrator to “distinguish among classes, types, and sizes of sources within a category or subcategory in establishing emission standards.” The current sterilizers NESHAP reflects different emission standards based on source size, and we will consider the need for such flexibility in our upcoming rulemaking for this source category.

As you requested, your comments have been placed in the dockets for both rulemakings.<sup>2</sup> I hope this information has been helpful to you, and I look forward to our continued conversations as we work to address this priority chemical. If you have any questions, please contact me or your staff may contact Patricia Haman in EPA’s office of Congressional and Intergovernmental Relations at [haman.patricia@epa.gov](mailto:haman.patricia@epa.gov) or (202)-564-2806.

Sincerely,

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Anne L. Idsal  
Principal Deputy Assistant Administrator

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

May 13, 2020

OFFICE OF  
AIR AND RADIATION

The Honorable Jody Hice  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Hice:

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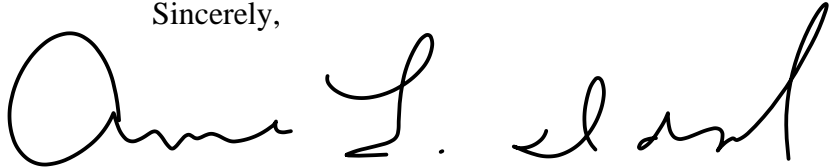
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The Honorable Henry Johnson  
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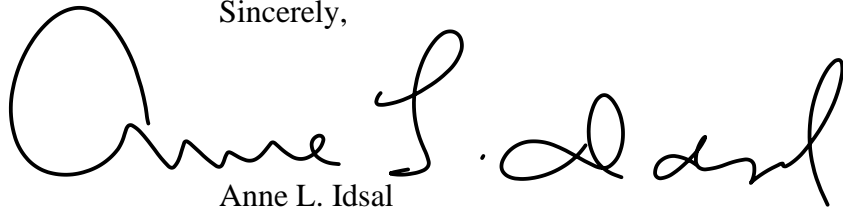
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The Honorable Susan Wild  
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You are correct in noting that EPA conducted ambient monitoring in Willowbrook. We recognized that agreeing to conduct monitoring in Willowbrook would provide us the opportunity to evaluate an available measurement method to make sure that it was able to provide reliable data. Indeed, the monitoring EPA conducted in that village has helped us to refine the method for monitoring this chemical, which is very challenging to measure. Based on what we learned in Willowbrook we have been able to provide a template for state and local governments who were interested in ethylene oxide monitoring. When requested, we have helped state and local agencies as they stand up monitoring in other parts of the country, including other areas in Illinois, Georgia, and Michigan. In addition, we recognized that monitoring in Willowbrook would provide us an opportunity to use the data we collected to verify the mathematical computer modeling, which we planned to use to conduct a comprehensive assessment of risk from the Willowbrook Sterigenics facility. As part of this work, we learned more about the significance of fugitive emissions, which was helpful for that risk assessment which was issued in 2019.

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At the same time we are reviewing the two NESHAPs, EPA is working to better understand potential background levels of ethylene oxide across the country. The Agency's national contract laboratory has measured ethylene oxide in air quality samples from 18 existing, longstanding monitors that are part of the National Air Toxics Trends Stations (NATTS) network and the Urban Air Toxics Monitoring Program (UATMP), and the Agency is training other laboratories to analyze for ethylene oxide at other monitors in these two networks. Ethylene oxide in the outdoor air remains challenging to measure. As we discussed in our March 31 meeting, EPA is working to improve its measurement methods for ethylene oxide in the outdoor air, with a focus on characterizing the chemical at lower concentrations and over shorter time periods. This work will be critical to helping us understand background ethylene oxide in different areas of the country.

#### *The IRIS value for ethylene oxide*

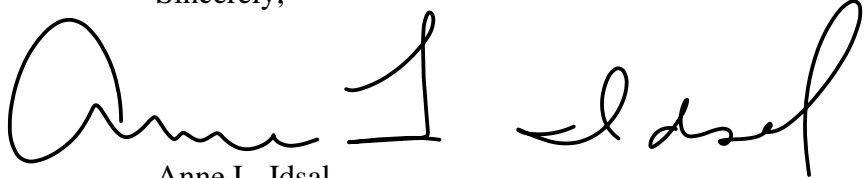
In your letter, you raised concerns about industry comments suggesting that EPA should reevaluate the IRIS value for ethylene oxide. As an Agency, we strive to use the best available science to guide our regulatory decisions. EPA's 2016 toxicity value for ethylene oxide was developed by EPA's Office of Research and Development and was based on human data from a large, occupational study and two rounds of review by the Agency's Science Advisory Board, as well as two rounds of public review. EPA has used the 2016 value in the technical analyses for recent Risk and Technology Reviews of several NESHAPs, including the recently proposed rule for chemical plants. In that proposed rule, EPA discussed uncertainties in the dose-response relationship underlying the toxicity value. In the proposed rule, the Agency also requested comments on the use of the EPA toxicity value and of other values. We are reviewing those comments and will consider those as we develop a final regulation.

*Addressing the diversity of industrial facility in the sterilizers rule*

Your letter encourages EPA to account for the diversity of the sterilization industry in its upcoming proposed rulemaking and asks the Agency to help small businesses comply. As we discussed in our recent meeting, about one-third of the facilities potentially affected by the sterilizers rule are small businesses. Because of this, we have convened an SBAR panel, which is expected to provide recommendations by late summer. The proposed regulation will include an appropriate time for facilities to comply, and EPA will provide compliance assistance. I also wish to note that section 112 of the CAA allows the Administrator to “distinguish among classes, types, and sizes of sources within a category or subcategory in establishing emission standards.” The current sterilizers NESHAP reflects different emission standards based on source size, and we will consider the need for such flexibility in our upcoming rulemaking for this source category.

As you requested, your comments have been placed in the dockets for both rulemakings.<sup>2</sup> I hope this information has been helpful to you, and I look forward to our continued conversations as we work to address this priority chemical. If you have any questions, please contact me or your staff may contact Patricia Haman in EPA’s office of Congressional and Intergovernmental Relations at [haman.patricia@epa.gov](mailto:haman.patricia@epa.gov) or (202)-564-2806.

Sincerely,

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Anne L. Idsal  
Principal Deputy Assistant Administrator

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<sup>2</sup> The letter is available in the “MON” docket at <https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0746-0166> and in the docket for the commercial sterilizers NESHAP at <https://www.regulations.gov/document?D=EPA-HQ-OAR-2019-0178-0139>





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

May 13, 2020

OFFICE OF  
AIR AND RADIATION

The Honorable David Scott  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Scott:

I am writing in response to your letter from March 27, 2020, about the U.S. Environmental Agency's (EPA) review of two regulations to address emissions of the chemical ethylene oxide: National Emissions Standards for Hazardous Air Pollutants (NESHAP) for miscellaneous organic chemical manufacturing, and the NESHAP for commercial sterilizers. I am pleased you had the opportunity to discuss the Agency's progress on these issues with Administrator Wheeler during the March 31, 2020, Congressional Ethylene Oxide Task Force call.

*Communicating about EPA rulemaking*

As EPA pursues its mission of protecting public health and the environment, addressing ethylene oxide is a high priority for the Agency. In your letter, you asked that EPA "be thinking about how to effectively communicate with the public every step of the way" as we go through the rulemaking process for the two regulations currently under review. As we discussed during our March 31 meeting, EPA has taken a number of steps to ensure an open and transparent rulemaking process. First, I signed proposed amendments to the NESHAP for miscellaneous organic chemical manufacturing (often referred to as "the MON") on November 1, 2019, and EPA made a copy of the proposed rule available on its website that same day. Second, the proposal was published in the Federal Register on December 17, 2019<sup>1</sup>. Third, EPA held two public hearings on the proposed rule: one on January 14, 2020, in Houston, Texas; and the other on January 16, 2020, in Washington, D.C. Fourth, the Agency held a public webinar to walk through the proposed rule on January 21, 2020. Finally, EPA provided a lengthy public comment period, which was extended to March 19, 2020; the public had access to the proposed rule for four and a half months prior to the comment deadline. EPA staff have been reviewing the more than 5,000 comments received on the proposed rule as they develop a final rule. EPA is under a court-ordered deadline to take final action on the MON by May 29, 2020.

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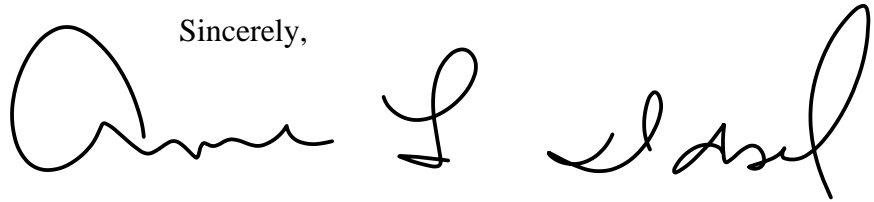
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